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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,111	03/10/2004	Dario Norberto R. Carrara	88066-7900	5916

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EXAMINER	
SCHLIENTZ, NATHAN W	
ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
11/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@winston.com
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Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/798,111	**Applicant(s)** CARRARA ET AL.	
	Examiner Nathan W. Schlientz	**Art Unit** 1616	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 November 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *03 November 2010*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3-11,13,15-26,29-31,37,40-47 and 56-68*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/John Pak/
Primary Examiner, Art Unit 1616

Continuation of 5. Applicant's reply has overcome the following rejection(s): rejection of claim 27 under 112, 2nd; rejection of claims 60 and 66-68 under 112, 2nd; rejection of claims 60 and 68 under 102(b) as being anticipated by WO 02/11768; and rejection of claims 1, 3-8, 10, 11, 13, 15, 20, 22, 37, 40-43, 45-47, 56, 57, 60-62 and 68 under 102(e) as being anticipated by US 7,030,104 and US 2003/0181430.

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 3-5 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims recite or depend from a claim that recites "between about", "between about… to about…" and "between… to about…." in references to concentration ranges. However, "between" implies a specific range with definite end values, whereas "about" encompasses other values close to the end values. Therefore, the scopes of the ranges are not clearly defined.

Applicant argues on page 12 that the dependent claims fall under and within the scope of the independent claims so they are also definite for that reason while still providing some latitude for the precise amounts that are suitable for the invention. However, the examiner respectfully argues that the recitations "between about", "between about… to about…" and "between… to about…." are indefinite since "between" implies values that fall within a specific range, whereas "about" encompasses values that are close to the recited values. Therefore, the range being claimed is not clearly defined.

Claims 1, 3-8, 10, 11, 13, 15, 20, 22, 37, 40-43, 45-47, 56, 57, 60-62 and 68 are rejected under 35 U.S.C. 102(a) as being anticipated by Gray et al. (WO 02/22132; US 7,030,104 is the English-language equivalent and is relied upon herein) for the reasons of record.

Applicant argues on page 13 that Gray et al. is not an effective prior art reference against the present application, and states that the Gray PCT application was published within one year of the filing of applicant's earliest provisional application. The examiner respectfully argues that under 35 U.S.C. 102(a) a person shall be entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent. Since Gray et al. was published within one year of the filing of applicant's earliest provisional application it is available prior art under 35 U.S.C. 102(a).

Applicant further argues that claims 1, 37 and 60 now recite formulations that are not disclosed by Gray et al., but applicant does not provide any specific argument as to what limitation of the instant claims is not disclosed by Gray et al. The examiner respectfully argues that Gray et al. disclose gels comprising 0.4 wt.% nomegestrol acetate or 0.1 wt.% estradiol, 0.5 wt.% carbopol gelling agent, 6 wt.% propylene glycol, 5 wt.% Transcutol (monoethyl ether of diethylene glycol), 0.05 wt.% EDTA, 0.3 wt.% triethanolamine, 45 wt.% ethanol and water to 100 wt.% (Table 1, G29-287 and Tx11323 batch-12). Therefore, Gray et al. anticipates the instant claims.

Applicant further argues that the instant invention was completed prior to the March 11, 2002 publication date of the Gray PCT application (published March 21, 2002), as evidenced by the Rule 131 declaration signed by inventor Dario Carrara. However, as indicated above, the declaration is not entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit was not earlier presented. WO 02/22132 was cited in the non-final Office action mailed 7 December 2009, and the rejection maintained in the final Offic acition mailed 20 May 2010. Applicant has not provided good and sufficient reasons why the affidavit was not presented after the non-final Office action but before prosecution was closed with the mailing of the final Office action.

Claims 1, 3-11, 13, 15-26, 29-31, 37, 40-47 and 56-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gray et al. (WO 02/22132), in view of Dudley et al. (US 6,503,894), Labrie (US 5,955,455), Catherino et al. (J. Steroid Biochem. Molec. Biol., 1995) and Wang et al. (The Journal of Clinical Endocrinology and Metabolism, 2000) for the reasons or record.

Applicant's arguments are the same as above and thus the examiner's response above is incorporated herein by reference.